November 17, 2022

Hon. Magistrate Judge Laurel Beeler
United States District Court – Northern District of California
San Francisco Courthouse, Courtroom B –15th Floor
450 Golden Gate Ave.
San Francisco, CA 94102

Re: *In re: Da Vinci Surgical Robot Antitrust Litigation*, 3:21-cv-03825-VC
Joint Letter re: Discovery Dispute

Judge Beeler,

In accordance with this Court's Standing Order regarding discovery disputes, defendant Intuitive Surgical, Inc. ("Intuitive") and third party Alliance Healthcare Partners, LLC ("Alliance") submit this joint letter. The issue before the Court is whether to grant Intuitive's Application for an Order compelling Alliance to comply with Intuitive's subpoena (the "Subpoena"). (Attached as Exhibit A are the Subpoena and Alliance's Objections.) The parties met and conferred via teleconference on July 15 and by email on July 22 and 27, but did not resolve their dispute. On August 5, Intuitive filed a motion to compel in the United States District Court for the District of Arizona, where Alliance is located. On October 28, that court transferred Intuitive's motion to this Court pursuant to Fed. R. Civ. P. 45(f). *In re Alliance Healthcare Partners, LLC*, No. MC-22-00033-PHX-DWL, 2022 WL 16527952 (D. Ariz. Oct. 28, 2022). On November 15, lead counsel met and conferred via teleconference, but did not resolve their dispute.

I. Intuitive's Position

Through the Subpoena, Intuitive seeks documents related to Alliance's efforts to obtain clearance pursuant to Section 510(k) of the Food, Drug and Cosmetic Act ("510(k) clearance") from the United States Food and Drug Administration ("FDA") for the remanufacturing of EndoWrist surgical instruments to extend the safety use limits Intuitive builds into those instruments; the subpoena also seeks documents relating to Alliance's role in marketing those remanufactured instruments. The documents that Intuitive seeks are relevant—indeed, highly important—to the issues underlying plaintiffs' claims in this case.

Intuitive seeks to ensure patient safety by enforcing FDA-cleared use limits for EndoWrists—generally ten uses. Plaintiffs challenge Intuitive's efforts, alleging that "EndoWrists could be used for dozens—and in some cases over 100—procedures, if inspected and repaired as needed between surgeries." (ECF No. 52, Consolidated Am. Class Action Compl. ¶ 109.) The availability of that remanufacturing, as well as FDA's requirement that it be performed only with 510(k) clearance (which no third party had until six weeks ago) are therefore core issues in this case.

Plaintiffs' allegations mimic assertions by Restore Robotics LLC ("Restore"), an entity from which plaintiffs allege they would have purchased remanufactured EndoWrists absent Intuitive's alleged misconduct. (*See id.* ¶¶ 122, 155-56.) Restore and Alliance have had an

ongoing business relationship relating to the remanufacturing of EndoWrists and the application for 510(k) clearance, although the actual nature and scope of that relationship remains murky.

In February 2021, Alliance filed an application seeking 510(k) clearance to extend the permitted uses for one type of EndoWrist by ten uses (i.e., one reset of the instrument's use counter). Restore has represented to another court that this application was filed on its behalf, but it was in fact filed on behalf of Iconocare Health Solutions, a shell company affiliated with Alliance. On September 30, 2022, the FDA cleared that application. The ownership and future status of that clearance are unclear. During a deposition on October 25, 2022, Restore's CEO claimed that Restore has exclusive rights to that clearance, but he also testified that Alliance and its affiliate, Innovative Health, would perform the remanufacturing pursuant to a contract that is yet to be negotiated. Meanwhile, a ***different*** Alliance affiliate—Encore Medical Device Repair—has begun advertising the remanufacturing service and claims to have exclusive distribution rights to FDA-cleared remanufactured EndoWrists.

The Subpoena seeks Alliance's documents related to the 510(k) application (RFP nos. 5-9), the pricing and costs of remanufactured EndoWrists (RFP no. 2), and Alliance's relationship with Restore (RFP nos. 4, 10). Alliance initially refused to produce all requested materials, aside from an incomplete email chain between Alliance and the FDA. But on October 24, 2022, Restore—in connection with its own lawsuit against Intuitive—produced some of the requested materials, which were identified by running a single search term ("K210478," the FDA-assigned name for the Iconocare 510(k) application) across the emails of two Alliance personnel. Alliance, which is represented by the same counsel as Restore, has represented that those documents can be used in this case. The produced documents confirm that Alliance personnel have been marketing remanufactured EndoWrists to putative class members here.

Alliance refuses to produce any other materials responsive to the Subpoena, though it does not dispute their relevance. Alliance's arguments are unavailing and should be rejected.

First, Alliance's undue burden objection is unsubstantiated. The Subpoena is targeted and narrow, seeking documents created since April 1, 2021 related to Alliance's efforts to obtain 510(k) clearance to extend EndoWrist use limits, its marketing of remanufactured EndoWrists, and its relationship with Restore. Alliance has offered no basis to conclude that searching for the requested materials would be burdensome. Indeed, Alliance's counsel objected to producing any additional documents without even running a search term hit report.

Second, Alliance's confidentiality concerns are adequately addressed by the protective order in this action. (ECF No. 65.) Not only is that protective order sufficient to protect Alliance's interest in confidentiality, but at the behest of counsel for Alliance and Restore, Intuitive agreed to a new "Outside Counsel Only" tier of protection in order to dispel any confidentiality concern. (ECF No. 105.)

Third, the requested materials need not be essential to justify an order compelling compliance with the Subpoena. In fact, the case that Alliance cites did not require the materials to be "essential," but instead "balance[d] the relevance of the discovery sought, the requesting party's need, and the potential hardship to the party subject to the subpoena." *Gonzales v. Google, Inc.*, 234 F.R.D. 674, 680 (N.D. Cal. 2006) (ordering production of third party's

confidential business information). Here, that balancing test weighs heavily in favor of granting Intuitive's requested relief, not only because the burden on Alliance is unsubstantiated, but because Alliance is the only entity that has obtained 510(k) clearance to remanufacture EndoWrists, and it has been marketing those instruments to putative class members. As a result, Intuitive expects that the materials it seeks will be highly important to key issues in this case. For instance, Intuitive expects that these materials will illustrate the difficulty that Alliance encountered—over more than nineteen months—seeking 510(k) clearance to add just ten additional uses to a single EndoWrist. Evidence of that difficulty would cast significant doubt on plaintiffs' claims that Intuitive's use limits are arbitrary and unassociated with safety. This evidence is also likely to cast light on the murky question of whether Restore—from which plaintiffs assert they would have purchased remanufactured instruments—ever had any real prospect of obtaining 510(k) clearance, or has any right even today to the single clearance that Alliance recently obtained. Intuitive also expects that the requested materials will address: the reality that (contrary to plaintiffs' allegations) extending EndoWrist use limits requires 510(k) clearance; the difficulty of selling remanufactured EndoWrists to hospitals without that clearance; and efforts by Alliance and Restore to gauge hospital interest (or the lack thereof) in remanufactured EndoWrists that, pursuant to the recent clearance, can only be subject to one use counter reset. Each of these issues bears directly on plaintiffs' claims.

II. Alliance's Position

Since the filing of the motion, Restore and Alliance collected and produced the submissions to the FDA, including testing data, regarding K210478 on September 19. Restore and Alliance then collected and produced thousands of pages of emails and attachments from the email accounts of Rick Ferreira and Rafal Chudzik that referenced K210478 on October 24. Thus, Alliance – despite the lack of a proper showing by Intuitive – has addressed the questions raised in the motion.

In its motion, Intuitive raised three – and only three – categories of "relevant" documents:

- "Documents related to Alliance's efforts to assist Restore to obtain 510(k) clearance" are relevant to a question in the class action whether the FDA requires a 510(k) "before an IRRC may lawfully extend EndoWrist use limits." Application at 7-8.

  Alliance has now searched and produced communications with the FDA.

- "[T]esting data submitted in connection with the 510(k) application" may be relevant to analyzing whether repaired instruments can be substantially equivalent to the new instruments. Application at 8.

  Restore and Alliance have now produced all testing data for K210478.

- "Alliance's documents will cast significant doubt on the plaintiff hospitals' claim that EndoWrists could be used 100 or more times by IRRCs." Application at 8.

  Restore and Alliance have not tested the instruments to failure.

In any event, the law is clear for non-parties under Rule 45. Since neither Restore nor Alliance is a party to the class action,[1] Intuitive can only acquire Alliance's remaining confidential research, development, and commercial information if it "shows a substantial need for the . . . material that cannot be otherwise met without undue hardship." Fed. Civ. Proc. 45(d)(3)(C)(i). In other words, it must be "essential to a judicial determination" in the class action. *Gonzales v. Google, Inc.*, 234 F.R.D. 674, 686 (N.D. Cal. 2006). Then, and only then, may a court rely on specified conditions like a protective order to direct production. Fed. R. Civ. Proc. 45(d)(3)(C).

Of course, Intuitive is a $5 billion company – and the original manufacturer of the instruments at issue – with thousands of employees and five testifying experts in *Restore v. Intuitive* alone. Alliance is a small company that happens to have assisted one of several ISOs in this market. Restore also happens to have a trial starting against Intuitive on February 6, 2023 in the Northern District of Florida. The proposed term searches here are far beyond the scope of the motion and Intuitive's needs in the class action. They are an attempt to harass Restore on the eve of trial in its own case against Intuitive.

Regulatory Requirements. Intuitive has its own regulatory department and litigation experts that can speak to any requirement for a 510(k). In fact, Intuitive knows that the FDA has never required a 510(k): the agency has never issued a warning letter or taken enforcement action against any company for extending the EndoWrist usage limits without a 510(k). Most recently, Intuitive itself sold extended use instruments for nearly two years before receiving a 510(k). In any event, Alliance is not responsible for proving a legal requirement of the FDA for Intuitive in its litigation with hospitals through one search and review after another of thousands of emails.

Testing Data. There was no need for production of the testing data in the first place. Restore is just one of many ISOs competing or looking to compete in this market with competing technologies. The success of one technology does not prove or disprove that other technologies in existence or development could or could not be deployed safely. In any event, the FDA cleared the 510(k) submission from Alliance confirming that the FDA believes that the Restore remanufactured instruments could be sold safely under their own label. Nevertheless, Restore and Alliance produced the testing data after the filing of the instant motion. Nothing more is needed from Alliance because we know nothing more was needed from Intuitive. Intuitive concedes that it has not conducted such a broad term search itself of emails for its own 510(k) application for extended use instruments (K214095).

Usage Limits. The hospital plaintiffs apparently allege that "EndoWrists could be used 100 or more times following inspection and 'repairs' by IRRCs." Application at 8. Intuitive can seek proof of that allegation from plaintiffs. In addition, Intuitive has its own engineers and experts that presumably tested the instruments to failure and can speak to the useful limits of their own

[1] Restore Robotics hired Alliance to assist Restore in developing technology for resetting usage limits and obtaining clearance for remanufacturing instruments under its own label. Restore brought antitrust claims in *Restore Robotics LLC, et. al v. Intuitive Surgical, Inc.*, No. 5:19cv55-TKW-MJF (N.D. Fl. Feb. 27, 2019). The Court denied summary judgment and specially set trial for February 6, 2023. Mr. Berhold represents Restore and Alliance in that litigation.

instruments. Furthermore, Intuitive is aware that Restore and Alliance did NOT test the instruments to failure. Restore-00089994. Again, Alliance is a small company with less than $2 million in annual sales. Alliance has been assisting Restore in developing one form of technology to reset the usage limits for an additional cycle of 10 uses. Alliance is not responsible for proving or disproving an issue for Intuitive in its litigation with hospitals through one search and review after another of thousands of emails.

In sum, Intuitive lacks substantial justification for continuing with its motion. Alliance has already incurred a substantial burden in conducting three searches and reviews of thousands of documents. Intuitive has not demonstrated anything approaching a substantial need under Rule 45 for a fourth search of documents regarding regulatory requirements or product safety. In fact, Intuitive never had a substantial need for any of the documents for purposes of the class action. Alliance has never done business with any of the named plaintiffs, and their technology is one of several in existence or development in the market. The term searches are overly broad (FDA, 510, Iconocare, EndoWrist, davinci, da Vinci) or are far afield from the requests in the motion (Encore, Milano, HCA, UHS, and Centennial). For example, there are 4,960 hits (3.5 gigabytes) in the Alliance email account for Rick Ferreira that refer to FDA alone from the close of discovery in *Restore v. Intuitive*.

Moreover, Intuitive demands that Alliance search emails at Innovative Health. Innovative Health is a separate company under different ownership and control. Restore and Alliance should be getting ready for their trial rather than chasing down thousands more emails in a fourth search and review. At this point, the motion is merely a fishing expedition to try to circumvent the discovery deadline in *Restore v. Intuitive* and harass Restore and its business partners ahead of trial in *Restore v. Intuitive*.

III. Each Party's Final Proposed Compromise

Intuitive: Intuitive's final proposal is that Alliance should produce documents responsive to the Subpoena by searching Rick Ferreira's and Rafal Chudzik's Alliance and Innovative Health email accounts, using the following search terms: "*FDA*," "*510*," "*Iconocare*," "*EndoWrist*," "*davinci*," "*da Vinci*," "*Encore*," "*Milano*," "*HCA*," "*UHS*," and "*Centennial*." These terms are more comprehensive—and likely to capture relevant communications in ordinary parlance—than the one search term Alliance used (i.e., "K210478").

Alliance: While this application was pending, Alliance compromised its position on responding to this subpoena multiple times to try to resolve the dispute. Alliance had previously consented to the use of its prior production in *Restore v. Intuitive* by both sides in the class action. After the filing of the motion, Alliance collected, reviewed, and produced the submissions to the FDA in *Restore v. Intuitive* and consented to their use in the class action. Alliance subsequently collected, reviewed, and produced all emails since the close of discovery in *Restore v. Intuitive* using the term search "K210478," totaling thousands of pages. Tellingly, Intuitive refused to include those facts in the joint introduction at the beginning of this letter. Having compromised its position unilaterally, not once but twice, to satisfy the demands in the motion, Alliance proposes that Intuitive withdraw this motion, which has never had any justification.

Dated: November 17, 2022

Respectfully submitted,

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